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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,287	12/17/2001	James M. Lipton	259/060US	7625
34055	7590	08/11/2004	EXAMINER	
PERKINS COIE LLP			SNEDDEN, SHERIDAN	
POST OFFICE BOX 1208				
SEATTLE, WA 98111-1208			ART UNIT	PAPER NUMBER
			1653	
DATE MAILED: 08/11/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/023,287	LIPTON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sheridan K Snedden	1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 4-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/8/03, 3/21/02, 12/17/03, 3/20/03</u>                                    | 6) <input type="checkbox"/> Other: ____.                                    |

### **DETAILED ACTION**

1. The restriction requirement of Office Action mail 10/01/2003 is withdrawn. The restriction requirement was made in error and directed to claims not consistent with the current application.
2. Applicant's amendment of claims 1-8, 14-15, 21-22, 26, 29, 30, 33, and 34 file in Paper filed 10/1/2002 is acknowledged.

### ***Election/Restrictions***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-3, drawn to a veterinary composition containing a peptide comprising KPV, classified in class 530, subclass 350.
  - II. Claims 4-6, drawn to a method of treating animal pruritis with a veterinary composition containing a peptide comprising KPV, classified in class 514, subclass 2.
  - III. Claims 7-13, drawn to a veterinary composition containing a peptide comprising KPV and an anti-inflammatory, classified in class 530, subclass 350.
  - IV. Claims 14-20, drawn to a method of treating animal pruritis with a veterinary composition containing a peptide comprising KPV and an anti-inflammatory, classified in class 514, subclass 2.
  - V. Claims 21-24, drawn to a veterinary composition containing a peptide comprising KPV and an antibiotic, classified in class 530, subclass 350.

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- VI. Claims 25-28, drawn to a method of treating animal pruritis with a veterinary composition containing a peptide comprising KPV and an antibiotic, classified in class 514, subclass 2.
- VII. Claims 29-32, drawn to a veterinary composition containing a peptide comprising KPV and an antifungal, classified in class 530, subclass 350.
- VIII. Claims 33-36, drawn to a method of treating animal pruritis with a veterinary composition containing a peptide comprising KPV and an antifungal, classified in class 514, subclass 2.

4. The inventions are distinct, each from the other because of the following reasons:

The products of inventions I, III, V and VII are directed to pharmaceutical products comprising distinct ingredients making the compositions suitable for treating different patient population suffering from a unique set of symptoms. Therefore, inventions I, III, V and VII are patentably distinct.

The methods of inventions II, IV, VI and VIII require different products and steps and have different endpoints. Therefore, inventions II, IV, VI and VIII are patentably distinct.

Inventions I, III, V and VII are related to invention II, IV, VI and VIII, respectively, as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of I,

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III, V and VII may be used in materially different processes, such as treating different patient populations suffering from distinct symptoms, for example.

5. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-VIII, restriction for examination purposes as indicated is proper.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In*

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*re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. During a telephone conversation with David Devlin on August 3, 2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-3. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-36 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A review of the full content of the specification and the prior art indicates that modifications to the peptides recited in claim 2 would have significant influences on the function of the variants. As such, the structure of the molecule having biologically equivalent function cannot be envisioned or predicted. In light of these considerations, applicant does not have possession of all polypeptides or compounds that are biologically equivalent to the peptides recited in claim 2.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipton *et al.* (WO 00/56353, IDS). Lipton *et al.* teaches the peptides of SEQ ID NO: 1, 3, and 4 recited in the present claims. The claims of Lipton *et al.* recite the composition of the above peptides and a carrier. At page 7 of Lipton *et al.*, a liquid-based carrier is taught, specifically as a cream, gel, spray, or foam, which reads upon the Applicant's recitation of a shampoo or cream. The compositions of Lipton *et al.* are applied topically for treating infection and/or inflammation. Thus, the reference clearly anticipates the invention as recited in the claims.

***Conclusion***

10. No claims are allowed.

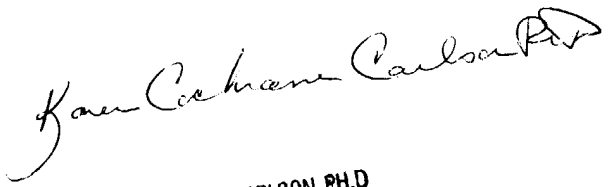
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS  
August 4, 2004

SKS

  
KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER